

# Notice of Allowability

## Application No.

09/834,110

## Examiner

Joseph T. Voitach

## Applicant(s)

HEWLITT ET AL.

## Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

☒ This communication is responsive to March 18, 2004.

☒ The allowed claim(s) is/are 25,26,31-33,35,37,39-41 and 43-49.

☒ The drawings filed on April 12, 2001 are accepted by the Examiner.

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some\* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

☒ Notice of References Cited (PTO-892)

☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☐ Notice of Informal Patent Application (PTO-152)

☒ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_.

☐ Examiner's Amendment/Comment

☒ Examiner's Statement of Reasons for Allowance

☐ Other \_\_\_\_\_.

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### **DETAILED ACTION**

This application filed April 12, 2001, claims benefit to provisional applications 60/198,806, filed May 13, 2000, and 60/232,301, filed September 12, 2000.

Applicants amendment filed March 18, 2004, has been received and entered. Claims 1-24, 27-30, 34, 36, 38 and 42 have been canceled. Claims 25, 26, 31-33, 35, 37, 39-41 and 44 have been amended. Claims 46-49 have been added. Claims 25, 26, 31-33, 35, 37, 39-41 and 43-49 are pending and currently under examination.

### ***Election/Restriction***

As stated in the prior office action Groups I and II were rejoined because both groups could be examined without serious burden as they are drawn to a method for the treatment of the elected species of a degenerative disorder.

It is noted that the independent claims have been amended to encompass providing nitric oxide within the gastrointestinal tract of a subject who have disorders associated with lower levels of nitric oxide (claims 35 and 41) and specific disorders demonstrating lower nitric oxide levels are recited (claims 44 and 45). One of the characteristics of these various disorders is lower levels of nitric oxide and each represent a different species of disorder that would benefit from the expression and presence of increased levels of nitric oxide. Since the pending claims are limited to providing nitric oxide, Examiner would maintain that any disorder that would benefit from added levels of nitric oxide would be considered obvious

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over each other. Further, each of the specific types of disorders taught in the specification and recited in the claims represent at least one sub-species of the species of disorders subject to a restriction requirement (paper number 9). In light of the claim amendments for the methods to provide specifically nitric oxide to a subject, and in view of the fact that each of the different species of disorders subject to the restriction requirement would benefit from the administration of nitric oxide, the election of species is withdrawn because they would represent obvious methods of treatment. Specifically, the treatment in each case is affected by the presence of nitric oxide independent of the differences in pathology and thus, any type of disorder known in the art associated with lower levels of nitric oxide would be obvious targets for treatment by the instantly claimed methods. The search and consideration of the method encompassed by the pending claims would be coextensive for any type of disorder of the gastrointestinal alimentary tract as long as the disorder is associated with lower levels of nitric oxide as required by the claims.

Therefore, in light of the claim amendments and the reasons above, the election of species is withdrawn.

### ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

Withdrawing the election of species has obviated the basis of the objection to the claims. Amendments to the claims to delete "progeny thereof" and more specifically

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defining the stem cell delivered and the result of providing NO has differentiated the claimed method from that disclosed by Luo *et al.* and Keller *et al.*

With respect to the rejection made under 35 USC 112, first paragraph, it has been noted that a reasonable correlation must exist between scope of exclusive right to patent application and scope of enablement set forth in patent application (27 USPQ2d 1662 *Ex parte Maizel*). The specification provides several disorders which are associated with the loss of neuronal cells in the gastrointestinal tract of a subject. Further, the specification teaches that neuronal stem cells when transplanted into the gastrointestinal alimentary tract differentiate and subsequently express NOS and provide NO. Supplementary evidence provided in the form a declaration details experiments that demonstrate that providing expression of NOS and the production of NO can alleviate symptoms caused by the lack of NO. Given the guidance in the specification, the evidence of record and the amendments to the claims to encompass methods for providing nitric oxide that would ameliorate symptoms in subjects having disorders associated with lower levels of NO, the rejection is withdrawn. The instantly claimed method encompassed by the pending claims now encompasses a scope of methodology that is fully enabled by the present disclosure.

The closest prior art is that of Weiss *et al.* (US Patent 6,497,872) demonstrating that neuronal stem cells can be successfully transplanted into a subject and can be used in methods to express a gene of interest in a subject. Unlike Weiss *et al.* the present invention does not require a transgene, and relies on the observation that the transplanted neuronal stem cells can differentiate and provide nitric oxide to surrounding cells. Further, the invention of

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Weiss *et al.* focuses on providing factors to the central nervous system where the present invention is used to affect symptoms of the gastrointestinal tract.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

A handwritten signature in black ink, appearing to read "Joe Woitach", with a stylized, cursive script.

JOSEPH WOITACH  
PATENT EXAMINER